DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95109d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

HAND-DELIVERED

WARNING LETTER

FLA-05-04

November 23, 2004

H. David Wallick, CEO
Kegelmaster 2000 Ltd.
4722 Camphor Avenue
Sarasota, Florida 34231

Dear Mr. Wallick:

During a Food and Drug Administration (FDA) inspection of your establishment located in Sarasota, Florida, on August 6, 2004, an FDA Investigator determined that your firm manufactures the Kegelmaster 2000. The Kegelmaster 2000 is a device as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), and was cleared by FDA in 2002 for assisting women in the performance of Kegel exercises, which may help control stress urinary incontinence.

The above-stated inspection revealed that your devices are adulterated and misbranded under the Act for the reasons set forth below.

The devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System (QS) regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure of management with executive responsibility in establishing its policy and objectives for, and commitment to, quality and to ensure that the quality policy is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20. For example, your firm has not established and implemented procedures or policies to comply with the QS regulation requirements addressing the manufacture and distribution of the Kegelmaster device.

2. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA) and to document all activities related to CAPA as required by 21 CFR 820.100(a) and (b). For example, your firm has not established CAPA procedures to address complaints, returned product and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems and has not documented the results of CAPA activities.

3. Failure to maintain complaint files and procedures for receiving, reviewing, and evaluating complaints by a formally designated unit as required by 21 CFR 820.198(a).

The above stated inspection also revealed that your device is misbranded under section 502(a) of the Act in that the labeling for the device is false and misleading. The carton label states, "Tested and Approved by U.S. Department of Health and Human Services FDA Food and Drug Administration". The instruction manual reads, "Tested and Approved by the FDA". These statements are false and misleading because the device is not approved by FDA. Clearance for marketing your device through 510(k) premarket notification process does not in any way denote official approval of the device and any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding as described in 21 CFR 807.97.

Additionally, your website contains statements that the Kegelmaster 2000 is FDA-approved. See, e.g., www.kegelmaster2000.com/truth.html ("The FDA has approved the safety of the new Kegelmaster."). Such statements are not accurate because the Kegelmaster 2000 was cleared by FDA, not approved or licensed. Our understanding is that distributors of the Kegelmaster 2000 are required to include on their websites links to your corporate website. Because your website contains these false statements regarding approval under section 301 of the Act, you are causing the device to be misbranded by requiring distributors to link to your website.

We also note that the above-stated inspection revealed that your firm failed to develop, maintain, or implement written Medical Device Reporting procedures respecting the device, as required under 21 CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each applicable requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate corrective and preventive actions to address the deficiencies noted above.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket approval applications to which the Quality System regulation deficiencies relate will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be granted until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or the initiation of proceedings to impose civil money penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

If you have any questions about the contents of this letter please contact Mr. Couzins at (407) 475-4728.

Sincerely,

Emma R. Singleton
Director, Florida District